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JUNE 14, 1995

Signature

COMID 191

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

STEFAN MILTENYI et al.

Serial No.: 08/416,920

Filing Date: 21 April 1995

DIRECT SELECTION OF CELLS Title:

BY SECRETION PRODUCT

18×12.

Group Art Unit: Unknown

Unassigned Examiner:

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR § 1.97

Assistant Commissioner for Patents 20231 Washington, D.C.

Dear Sir:

The information listed below, which may be material to the examination of the above-identified application, was previously disclosed in several Information Disclosure Statements dated March 28, 1995 and January 19, 1993, both directed to the parent application Serial Number 07/965,934 (filed 10/21/92). Copies of the information were also previously submitted; therefore, copies are not included This protocol conforms with 37 CFR § 1.98(d) and The Examiner is respectfully requested to MPEP 609(A) (2). make this information of official record in the application. The information includes:

Medline® abstract of Barington et al., "An improved haemolytic plaque assay for the detection of cells secreting antibody to bacterial antigens" <u>J. Immunol. Met.</u> (1992) 146:129-137.

Medline® abstract of Barington et al., "A simplification of the enzyme-linked immunospot technique. Increased sensitivity for cells secreting IgG antibodies to Haemophilus influenzae type b capsular polysaccharide" J. Immunol. Met. (1992) 156:191-198.

Medline® abstract of Coco-Martin et al., "An isotype-specific spot-ELISA for the enumeration of antibody-secreting hybridomas and the determination of isotype switch variants" J. Immunol. Met. (1991) 145:11-18.

Medline® abstract of Conrad et al., "Immunoglobulin VH and VK genes of the BALB/c anti-foot-and-mouth disease virus (O1) VP1 response: cloning, characterization and transgenic mice" Mol. Immunol. (1991) 28:1201-1209.

Medline® abstract of Darveau et al., "Efficient preparation of human monoclonal antibody-secreting heterohybridomas using peripheral B lymphocytes cultured in the CD40 system"

J. Immunol. Met. (1993) 159:139-143.

Medline® abstract of Eriksson et al., "Amplified ELISPOT assay for the detection of HIV-specific antibody-secreting cells in subhuman primates" <u>J. Immunol. Met.</u> (1992) <u>153</u>:107-113.

Medline® abstract of Fischer et al., "Paucity of humoral response in patients to glioma-associated antigen(s): antigen localization by immunofluorescence" Adv. Exp. Med. Biol. (1991) 303:263-270.

Medline® abstract of Giordano et al., Repeated glucose stimulation reveals distinct and lasting secretion patterns of individual rat pancreatic B cells" <u>J. Clin. Invest.</u> (1991) 87:2178-2185.

Medline® abstract of Isolauri et al., "Local immune response in patients with cow milk allergy: follow-up of patients retaining allergy or becoming tolerant" <u>J. Pediatr.</u> (1992) 120:9-15.

Medline® abstract of Lalor et al., "Functional and molecular characterization of single, (4-hydroxy-3-nitrophenyl)acetyl (NP)-specific, IgG1+ B cells from antibody-secreting and memory B cell pathways in the C57BL/6 immune response to NP" Eur. J. Immunol. (1992) 22:3001-3011.

Medline® abstract of Liu et al., "Production of anti-tumor human monoclonal antibodies using different approaches" <u>Hum.</u> Antibodies Hybridomas (1993) 4:2-8.

Marder et al., "Selective cloning of hybridoma cells for enhanced immunoglobulin production using flow cytometric cell sorting and automated laser nephelometry" Cytometry (1990) <a href="https://doi.org/10.2016/j.com/10.2016/j.co

Medline® abstract of Nesheim et al., "Diagnosis of human immunodeficiency virus infection by enzyme-linked immunospot

assays in a prospectively followed cohort of infants of human immunodeficiency virus-seropositive women" <u>Pediatr.</u> <u>Infect. Dis. J.</u> (1992) <u>11</u>:635-639.

Medline® abstract of Quiding et al., "Intestinal immune responses in humans. Oral cholera vaccination induces strong intestinal antibody responses and interferon-gamma production and evokes local immunological memory" <u>J. Clin.</u>

Invest. (1991) 88:143-148.

Medline[®] abstract of Sakamoto et al., "Method for selecting anthocyanin-producing cells by a cell sorter" <u>Planta Med.</u> (1994) 60:253-259.

Medline® abstract of Shibata et al., "Clonal frequency analysis of B cells producing pathogenic anti-DNA antibody-associated idiotypes in systemic lupus erythematosus" Clin. Immunol. Immunopathol. (1992) 63:252-258.

Medline® abstract of Sparholt et al., "Detection of B-lymphocytes secreting antibodies to *Dermatophagoides* antigens" <u>Clin. Exp. Allergy</u> (1991) <u>21</u>:85-90.

Medline® abstract of Steenbakkers et al., "A new approach to the generation of human or murine antibody producing hybridomas" J. Immunol. Met. (1992) 152:69-77.

Medline® abstract of Ufimtseva et al., "Mink-mouse interspecific hybridomas" <u>Hybridoma</u> (1991) <u>10</u>:517-528.

Werner-Favre et al., "High IgE secretion capacity of human plasma cells" <u>Eur. J. Immunol.</u> (1993) <u>23</u>:2038-2040.

Köhler et al., "Immunoglobulin M Mutants" <u>Eur. J. Immunol.</u> (1980) <u>10</u>:467-476.

Nir et al., "Single-Cell Entrapment and Microcolony Development within Uniform Microspheres Amendable to Flow Cytometry", <u>Applied and Environ. Microbiol.</u> (1990) 56(9):2870-2875.

Nir et al., "Flow Cytometry Sorting of Viable Bacteria and Yeasts According to β -Galactosidase Activity", <u>Applied and Environ</u>. <u>Microbiol</u>. (1991) <u>56</u>(12):3861-3866.

International (PCT) Patent Publication No. WO 90/02334 (8 March 1990).

U.S. Patent No. 4,557,979 to Higginbottom et al., (10 December 1985).

International (PCT) Patent Publication No. WO 89/10758 (16 November 1989).

European Patent Application No. 0219309 (22 April 1987).

Ehrlich et al., "Marker and Function Analysis of Natural Killer and Alloreactive T Cells during Early Stages of Dimethylbenzanthracene Carcinogenesis", Nat. Immun. Cell Growth Regul. (1986) 5:305-316.

Greenstein et al., "Flow Sorting of Antigen-binding B Cell Subsets", <u>J. Immunol.</u> (1980) <u>124</u>(3):1472-1481.

Greenstein et al., "Functional Subsets of B Cells defined by Quantitative differences in Surface *I-A*", <u>J. Immunol.</u> (1981) 126:2419-2423.

Kleinberger et al., "Carcinogen-mediated co-activation of two independent genes in Chinese hamster cells", Carcinogenesis (1988) 9(6):979-985.

Letwin et al., "An Improved Clonal Excess Assay Using Flow Cytometry and B-Cell Gating", <u>Blood</u> (1990) <u>75(5):1178-1185</u>.

Marti et al., "Normal Human Blood Density Gradient Lymphocyte Subset Analysis", <u>Amer. J. Hematol.</u> (1985) <u>20</u>:41-52.

Michalevicz et al., (1989) "Characterization of Lympho-Myeloid-Erythroid-Megakaryocytic Stem Cells in Peripheral Blood of Hairy Cell Leukemia Patients", <u>Leukemia Res.</u> 13(10):915-920.

Slezak et al., "Fluorescent in Vivo Tracking of Hematopoietic Cells. Part I. Technical Considerations", Blood (1989) 74(6):2172-2177.

Slezak et al., "Cell-mediated Cytotoxicity" A Highly Sensitive and Informative Flow Cytometric Assay", <u>J.</u>
Immunol. Meth. (1989) <u>117</u>:205-214.

The information listed below, which may be material to the examination of the above-identified application, was previously cited in an Office Action dated March 18, 1993, directed to the parent application Serial Number 07/965,934

(filed 10/21/92). Copies of the information were also previously included in the application file; therefore, copies are not included herewith. This protocol conforms with 37 CFR § 1.98(d) and MPEP 609(A) (2). The Examiner is respectfully requested to make this information of official record in the application. The information includes:

Koga et al., "Synthesis and release of interleukin 1 by reoxygenated human mononuclear phagocytes" <u>J. Clin. Invest.</u> (1992) 90:1007-1015.

Parks et al., "Antigen-specific identification and cloning of hybridomas with a fluorescence-activated cell sorter"

Proc. Natl Acad. Sci. USA (1979) 76:1962-1966.

Weissman et al., "Only high-affinity receptors for interleukin 2 mediate internalization of ligand" Proc. Natl. Acad. Sci. USA (1986) 83:1463-1466.

This Information Disclosure Statement is submitted less than three months from the application filing date.

Accordingly, the applicants believe that no fee is due.

However, the Commissioner is hereby authorized to charge any fees which may be required by this paper to Deposit Account Number 03-1952.

Applicants would appreciate the Examiner's initialling and returning the Form PTO-1449, indicating that the references have indeed been considered and made of record herein.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Ву

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Date

June 14, 1995

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